

# AI Roadmap for Quality & Demonstration of New AI Features

François GUELY & Grégory DESGRANDCHAMPS

October 16th, 2025

3:00pm - 3:30pm	Afternoon Break		
	Ennov Regulatory	Ennov Quality	DocShifter
3:30pm - 5:00pm	<b>Part 1: The IDMP Preparation Playbook: Hard-won Insights from Experts</b> <b>Part 2: EMA Updates and Product Demo</b> Alice Merrill, Vanessa Espurz & Pierre Stanislawski	<b>AI Roadmap for Quality &amp; Demo of New AI Features</b> Grégory Desgrandchamps & François Guely	<b>Automated Content Prep with DocShifter</b> Paul Ireland
	Cheese and Wine Tasting Reception All Attendees Invited		



# Presenters

Bringing together the best in the industry



**François GUELY**

*Strategic Marketing Director*

François joined Ennov in 2011, after more than 20 years in the software industry. His responsibilities included managing a research laboratory, managing product management, and founding two companies.

At Ennov, he makes sure that Ennov stays at the forefront of technology innovation, both internally and through partnerships.

# Presenters

Bringing together the best in the industry



**Gregory DESGRANDCHAMPS**

*Product manager - Quality*

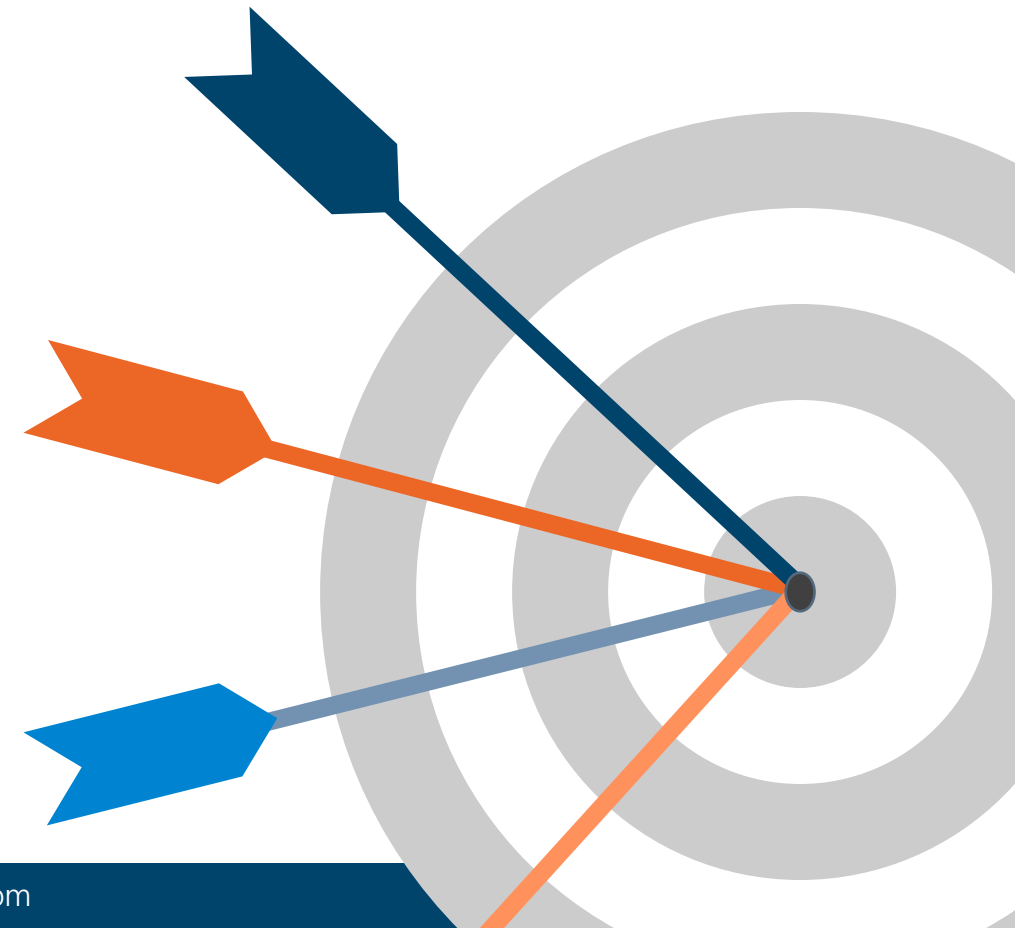
Greg joined the Ennov team in January 2024 after more than 20 years in the pharmaceutical industry. His responsibilities included the management of quality applications – among others the Ennov application - and compliance for computerized systems.

At Ennov, he makes sure that the quality solutions and associated deliverables meet the expectations of the industry. For this, Greg's experience on the other side of the fence is invaluable.

# Objectives

*Discover the latest and coming AI features for Quality*

*To enhance quality management for YOU!*



# Agenda

1 AI Quality Roadmap

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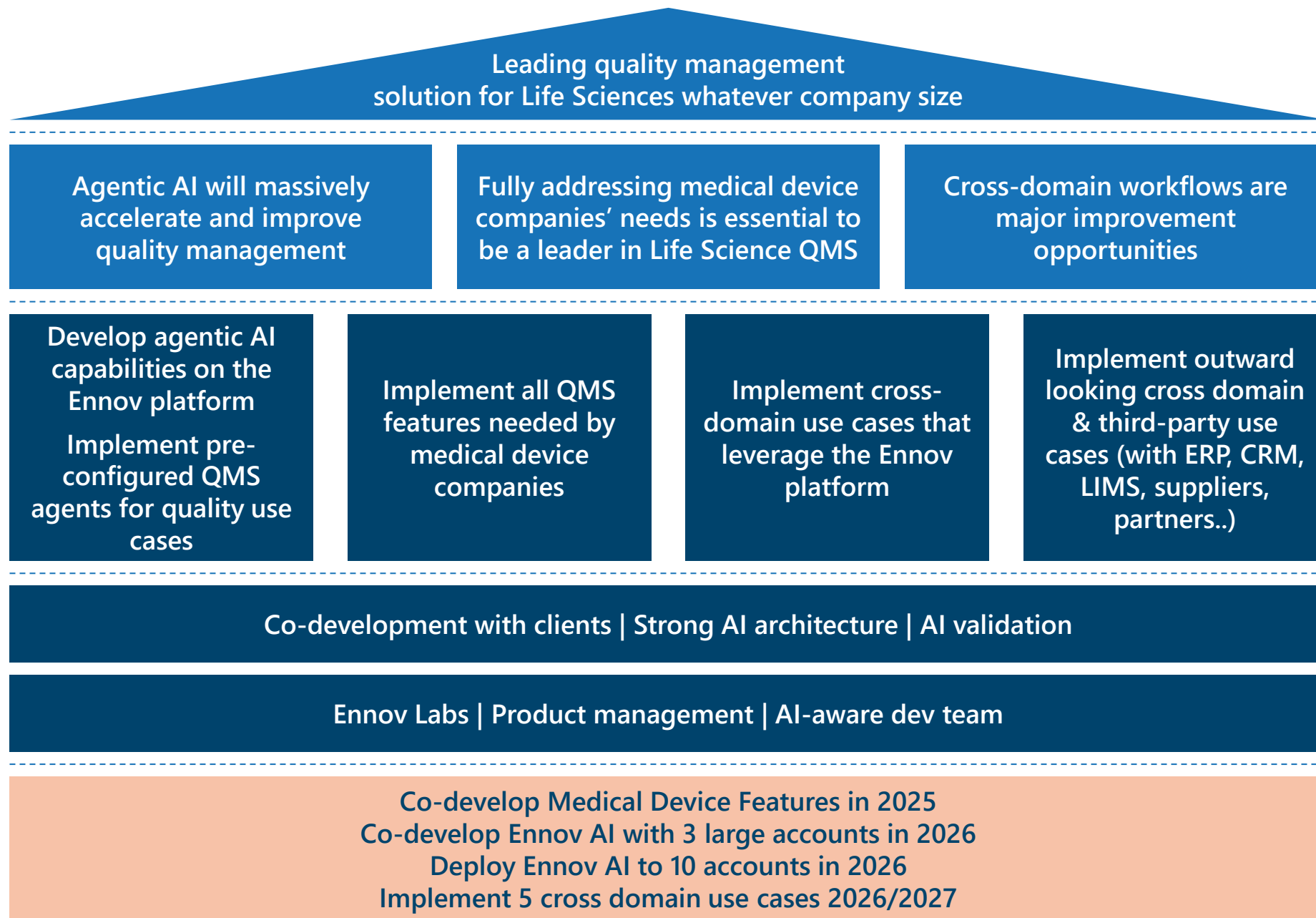
2 New AI features demonstration

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# 1 – AI Quality Roadmap

# Quality Management Strategic Narrative





# Ennov AI Roadmap – Focus on Quality

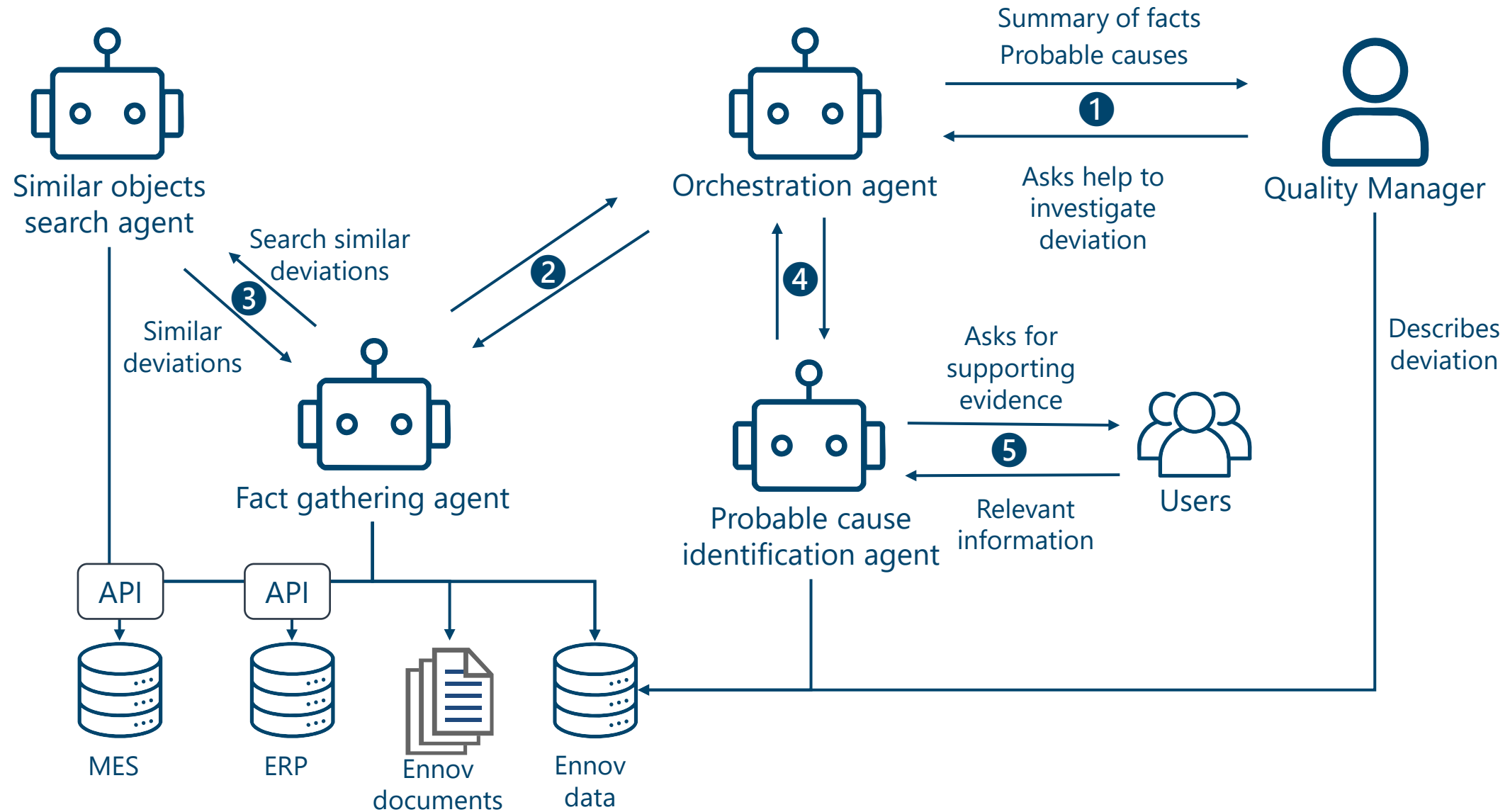
	April 2025	October 2025	April 2026	September 2026
<b>Ennov Platform</b>	Document summary & translation	Chatbot (RAG based)	Conversational Assistant MCP Server Prompt Library	Ennov Autonomic Agents Document Co-Author Microsoft Graph connector
<b>Quality</b>	<b>MCQ generation for Ennov Training</b>	<b>Multi-doc MCQ generation</b>	<b>Co-Investigator</b>	<b>AI Training Tutor Co-Trainer</b>
<b>Regulatory</b>	eCTD automatic classification Questions & commitments extraction from HA letters		HA answer draft generation Regulatory intelligence chatbot (FDA content)	Regulatory document generation template library ePI generation*
<b>Clinical</b>	eTMF document classification		Auto-coding for EDC	Patient visit transcription & CRF automatic entry* Clinical document generation template library
<b>Event</b>	Expense automatic intake			
<b>PV</b>	Automatic CV case entry	Automatic PV case entry	Duplicate case detection	Auto-assessment of cause-effect relationship



# Some Potential Agentic AI Use Cases in Quality Management

Domain	Agent	Main purpose	Agent	Main purpose
Deviations, NCs, OOS	Deviation triage agent	<ul style="list-style-type: none"> <li>Assess severity</li> <li>Classify category</li> <li>Auto-populate form</li> <li>Suggest containment steps</li> </ul>	Investigation agent	<ul style="list-style-type: none"> <li>Gather facts, trends, interviews</li> <li>Propose 5-why hypotheses</li> <li>Queries LIMS, MES, ERP</li> <li>Synthesizes evidence and gaps</li> </ul>
CAPA	CAPA planner agent	<ul style="list-style-type: none"> <li>Convert root cause analysis into structured CAPA (actions, owners, due dates, effectiveness criteria)</li> <li>Align with ICH Q10</li> </ul>	Global CAPA harmonization agent	<ul style="list-style-type: none"> <li>Detect similar CAPA across sites</li> <li>Consolidate content of similar CAPA to leverage learnings from them</li> </ul>
Change Control	Change orchestration agent	<ul style="list-style-type: none"> <li>Assess impact of change: processes, validation, stability, labeling</li> <li>Create impact matrix</li> <li>Propose qualification/validation plan</li> </ul>		
EDMS	Document consistency agent	<ul style="list-style-type: none"> <li>Detect contradictions across SOPs, Specifications, Batch records, QMS forms...</li> </ul>		
Training	Training tutor	<ul style="list-style-type: none"> <li>Adapts interactions to trainee knowledge level, detects knowledge gaps of trainee</li> </ul>	Compliance coach agent	<ul style="list-style-type: none"> <li>Delivers contextual learning on SOP updates</li> <li>Just-in-time coaching when in doubt</li> </ul>

# Agentic Investigation Agent



# Co-Investigator

Creation



Investigation



Review

- › Event seriousness auto-assessment
- › Identification and association of similar events
- › Investigation form assisted completion (findings, root cause, impacts...)
- › Identification and linking of relevant CAPA
- › Proposal of improved CAPA
- › Next Best Action(s) recommendation based on previous event(s) and their efficiency
- › Event (deviation, CC...) summary generation
- › Final event report generation

# AI Tutor

## Helping user train themselves



### AI training tutor

Helps a trainee learn the training material, by enabling conversations around the training material

Tutor avatar with Speech interaction

Assesses your level, recommends when to pass the MCQ



### Training / re-training suggestions

Suggests which trainings a trainee should do or redo, according to the role and the actions of the person on the system

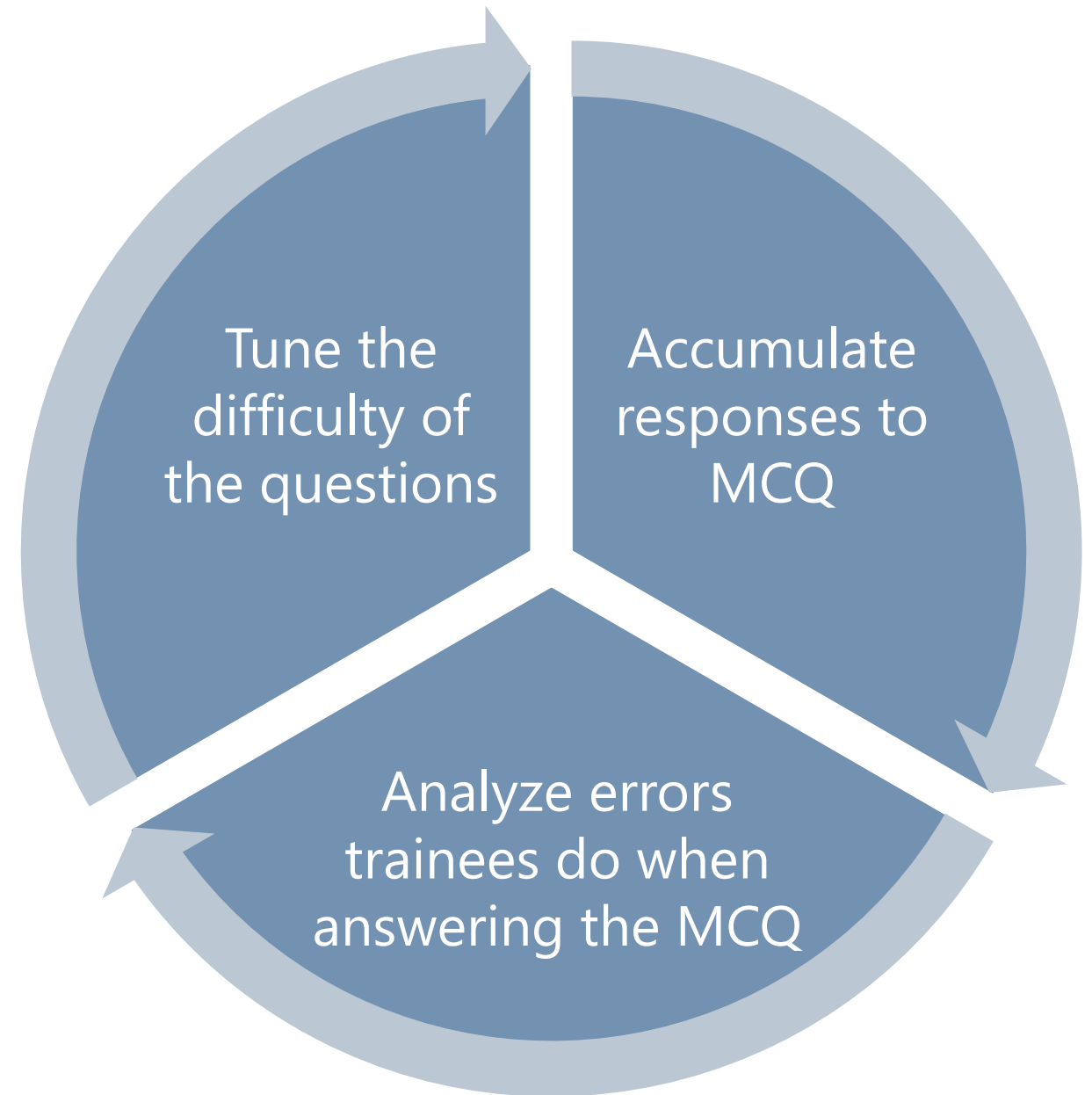


### On-demand training creation

Towards personalized training

# Co-Trainer

- › Training material improvement suggestions
  - › Content improvements
  - › Pedagogy, format
- › Training material generation
  - › Training outline
  - › Main content in each chapter
  - › Slides for each content chapter
- › Training results analysis
  - › Recommend best next actions



# Document Co-Author



## **Document drafting (authoring)**

- Template based document generation
- Prompts linked to document template
- Link to document guidance through prompt
- Revision history



## **Document auto-proofreading (advising)**

- Writing style
- Grammatical and syntaxis errors, spelling mistakes
- Document internal coherence check
- Coherence with guidance & other eDMS documents



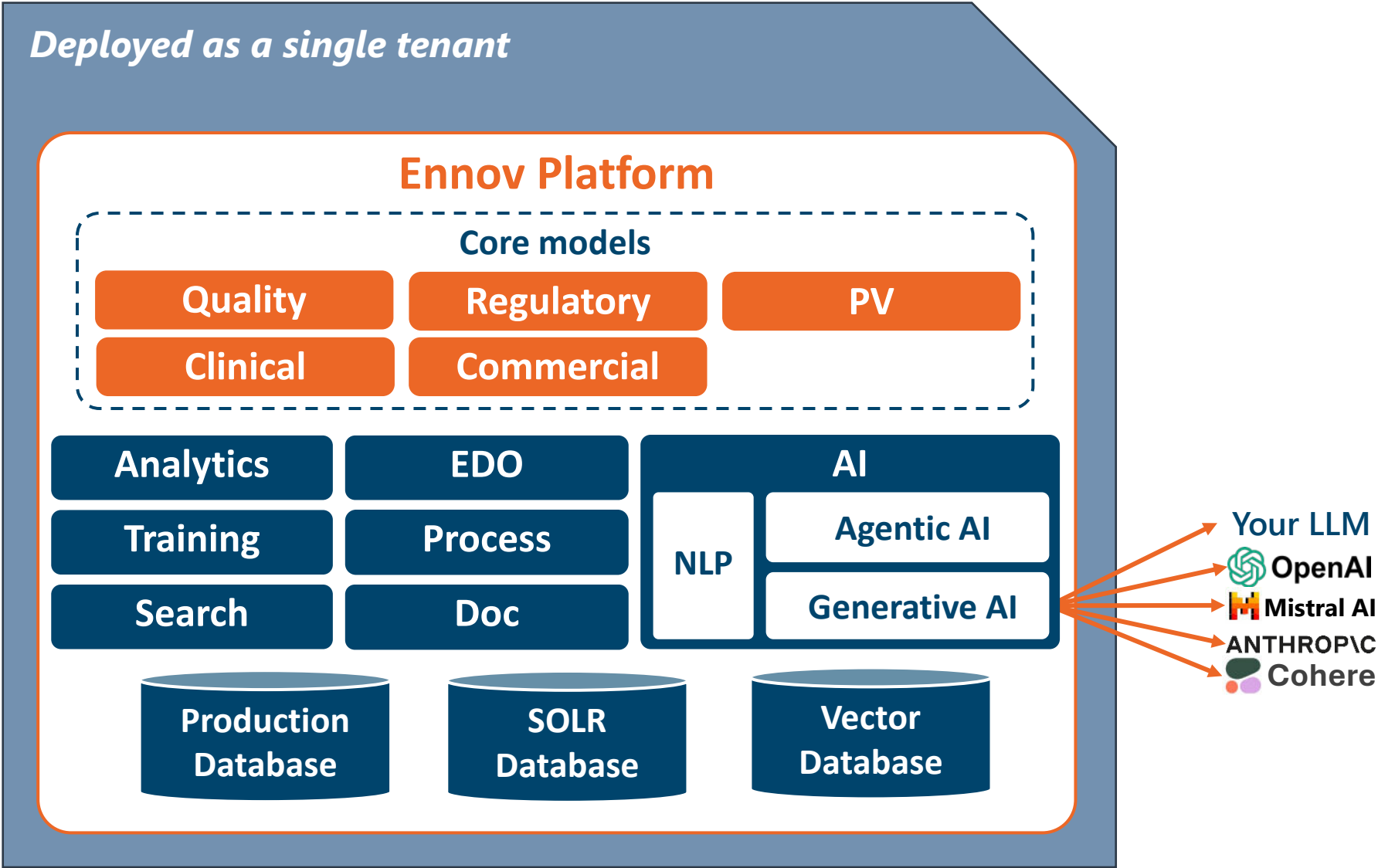
## **Document classification (assisting)**

- Metadata auto-filling
- Recipients suggestion...

# 2 – New AI features demonstration



# Infrastructure





# Ethics, Compliance & Regulatory Obligations

The use of AI is governed by various regulations

AI Act

GMP (A11 & A22)

21 CFR Part 11

RGPD, Data Act...

Key requirements

Risk based management

Transparency &  
Explainability

Privacy, Security,  
Intellectual property

Human oversight

**Responsible AI use demands transparency, validation, data integrity, and regulatory compliance**

# 01 AI Chatbot



- › Use data from the Ennov datasource (documents, processes) to formulate its responses
- › Subject to the Ennov AI license

10.4  
11.0

## 02 eDoc – Document translation



- › 2 modes
  - › Create a new translated document (record in eDoc)
  - › View "translated" document (no record)
- › Languages supported to date
  - › French, German, English, Chinese, Danish, Spanish, Italian, Japanese, Dutch, Polish, Portuguese, Russian
  - › Other languages on request
- › Some use cases:
  - › Corporate doc to affiliate
  - › Foreign auditors
- › Subject to license (AI)

## 03 eDoc – Document summary



- › 2 modes
  - › Create and insert in "Summary" field (record in eDoc)
  - › View document "summary" (no record)
- › Languages supported to date
  - › French, German, English, Chinese, Danish, Spanish, Italian, Japanese, Dutch, Polish, Portuguese, Russian
  - › Other languages on request
- › Some use cases:
  - › Multi lingual summary
  - › Contextual information
- › Subject to license (AI)

# Training is a regulatory requirement

- › In life sciences, skills mastery is a global regulatory requirement
- › FDA (21CFR p211 and p850), EMA (GMP Eudralex vol.4) impose on personnel in connection with GxP activities:
  - › Training
    - › Initial & continuous
    - › Adapted to responsibilities
  - › Qualification and Accreditation
    - › Demonstrate acquisition of skills
  - › Periodical review
    - › Audit and maintain skills
  - › Documentation and traceability



**FDA and EMA:  
Reading SOPs is Not  
Training,  
Training is Not  
Qualification**

10.3  
11.0

## 04 AI generated Training MCQs



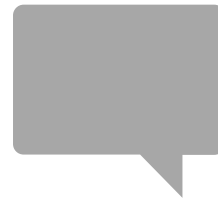
- › Feature to generate MCQs:
  - › On a document and/or,
  - › On a module (on all documents of the module)
- › Combine efficiency and compliance
- › MCQ in a minute!
- › Subject to the Ennov AI license

# 3 – Q&A and feedbacks

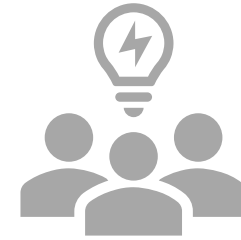




Questions



Feedbacks



Additional ideas or use  
cases



# Thank you for your attention!

